

REMARKS

Reconsideration of the present application in light of the above amendments and the following remarks is respectfully requested. Claims 1-8 and 10-16 are pending. Claim 1 has been amended to more specifically focus on one aspect of the subject matter without acquiescing to the rejections and merely to facilitate allowance. Specific support for the use of vital dyes is provided, *e.g.*, on page 9, lines 1-10. Claim 4 has been amended to correct a typographical error. Claim 10 has been amended to conform to the amendment of claim 1. No new matter has been added.

Claim Objections

Claim 4 stands objected to due to a typographical error. Applicant thanks the Examiner for pointing out the oversight and notes that the misspelling has been corrected in claim 4. Accordingly, Applicant respectfully request that this objection be withdrawn.

Rejection under 35 U.S.C. § 102(b) First Rejection

Claims 1-6 and 8-15 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Townsend *et al.* (WO 96/40980). In particular, the Action alleges that the cited reference teaches a composition comprising substrates and detectable markers, including those of the presently claimed invention.

Applicant traverses this ground for rejection and submits that each and every element of the claims of the present invention is not present in the cited reference. In particular, Applicant submits that the cited reference fails to teach a composition comprising both a vital dye and a substrate for an aminopeptidase that is substantially absent from a target organism.

Applicant submits that the present invention is primarily drawn to a novel method of detecting a target microorganism, which method generally comprises detecting total viable microorganisms using a vital dye, detecting non-target microorganisms using a substrate for an enzyme to present in the target enzyme, and comparing the amount of microorganism. In addition, the invention includes compositions that may be used to practice this method, including those presently claimed. In stark contrast, the method and related compositions described in

Townsend *et al.* are primarily directed to the use of a bacterial growth medium comprising three or more different enzyme substrates, each hydrolyzed by a different bacterial enzyme to produce a detectable signal. Furthermore, Townsend *et al.* contemplate the use of naturally-occurring enzyme substrates that include a nutrient moiety. Nowhere does Townsend *et al.* describe a composition comprising both a vital dye and a substrate for an aminopeptidase that is substantially absent from the target organism.

Applicant submits that the claims of the present invention have been amended to expedite prosecution and without acquiescence to this basis of rejection, to recite a composition comprising (1) a conditionally detectable marker, wherein said marker is a vital dye, and (2) a substrate for an aminopeptidase that is substantially absent from the target microorganism. Applicant submits that such a composition is not disclosed in the cited reference. The Examiner notes that in the Background of the Invention section, the cited reference teaches the use of tetrazolium to detect a microbe. However, the cited reference absolutely does not describe a composition comprising both tetrazolium (or any other vital dye) and a substrate for an aminopeptidase in microbe detection. Accordingly, Applicant submit that the cited reference fails to teach or suggest each element of the presently claimed invention and, therefore, does not anticipate the claimed invention. Applicant respectfully requests that this rejection be withdrawn.

Rejection under 35 U.S.C. 103(a), First Rejection

Claims 1-8 and 10-15 stand rejected as allegedly being obvious in light of Townsend *et al.* In particular, the Action alleges that Townsend teaches a composition for detecting viable bacteria, yeast, or fungi in a test sample by using detectable markers. The Action concedes that Townsend *et al.* does not specifically teach the composition comprising tetrazolium red, but alleges that one of skill in the art would have found it obvious in light of the teachings of Townsend *et al.* for the skilled artisan to use tetrazolium red in the composition of Townsend *et al.* with a reasonable expectation for successfully detecting microorganisms.

Applicant respectfully traverses this ground for rejection and submit that one of skill in the art would not view the presently claimed invention as obvious in light of Townsend *et al.* Indeed, the Examiner has failed to establish a *prima facie* case of obviousness, since the Action fails to establish that each element of the presently claimed invention is taught or

suggested by Townsend *et al.* Specifically, Townsend *et al.* does not teach or suggest the use of a vital dye in a composition further comprising a detectable substrate. Rather, Townsend *et al.* teaches a bacterial growth medium comprising three or more enzyme substrates, which each preferably comprise a nutrient moiety. Townsend *et al.* state in the Background of the Invention that previous attempts to measure bacterial concentration have included indicators that change color in the presence of a microorganism, but effectively dismiss the use of such dyes in their described composition, since they do not serve as a source of a required nutrient (page 2, lines 23-27). Thus, Townsend *et al.* actually teach away from the use of a vital dye in a composition further comprising a substrate for an aminopeptidase. Accordingly, the skilled artisan would not be motivated to include a vital dye, which does not comprise a nutrient moiety, in the composition described by Townsend *et al.* to achieve the claimed invention. Therefore, Townsend *et al.* fail to teach this element of the claimed composition, and Applicant respectfully requests that this rejection be withdrawn.

Rejection under 35 U.S.C. § 103(a), Second Rejection

Claims 1-8 and 10-16 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious in light of Townsend in view of Stern *et al.* (US Patent No. 5,891,709). The Action alleges that Townsend *et al.* teaches a composition for detecting viable bacteria, yeast, or fungi in a test sample by using detectable markers, and Stern *et al.* disclose using antibiotics to select for particular bacterial strains. The Action concedes that Townsend *et al.* does not specifically teach using tetrazolium red as a detectable marker or antibiotics as selection for particular bacterial strains.

Applicant respectfully traverses this ground for rejection and submits that one of skill in the art would not find the presently claimed invention obvious in view of Townsend *et al.* and Stern *et al.*, either alone or in combination. As noted above, Townsend *et al.* fails to teach a composition comprising a vital dye. Applicant submits that Stern *et al.* does not remedy the deficiencies of Townsend *et al.*, since Stern *et al.* also does not disclose a composition comprising a vital dye. Thus, Applicant submits that neither Townsend nor Stern *et al.* teach a composition for detecting a microorganism in a sample comprising both a vital dye and a

substrate that is substantially absent from the target microorganism. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Application No. 09/940,682
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Applicants respectfully submit that the claims remaining in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. Should any remaining issues exist, the Examiner is urged to contact the undersigned attorney at (206) 622-4900.

Respectfully submitted,
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